

REMARKS

Reconsideration of the application in view of the above amendments and following remarks is respectfully requested.

Claims 1-4, 8-12, 14, 17-28, 30, 70, 73, 74, 76, 78, 126-128, 426-429, 432, 435, 438, 441 and 444-447 were pending. Claims 426-429, 432, 435, 438, 441 and 444 are withdrawn as being directed to non-elected inventive Group II as identified in the Restriction Requirement dated April 2, 2008. Claim 1 has been amended without acquiescing to the rejections in the Office Action. Specifically, the limitations of claim 2 have been incorporated into claim 1. Claim 2 has accordingly been cancelled without prejudice to future prosecution in a related application. Claims 3 and 30 have been amended to update dependency in view of the cancellation of claim 2. No new matter has been added via the amendments. Claims 1, 3, 4, 8-12, 14, 17-28, 30, 70, 73, 74, 76, 78, 126-128, and 445-447 are now under consideration.

***Rejection under 35 U.S.C. § 102***

Claims 1-2, 4, 8-11, 17, 19-21, 24, 30, 78, 444 and 446-447 stand rejected under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent Publication No. 2001/0053931 issued to Hess *et al.* (hereinafter “Hess”).

As a preliminary matter, claim 2 has been cancelled herein without prejudice. Further, claim 444 has been withdrawn from consideration at this time. Therefore, this rejection as applied to claims 2 and 444 has been rendered moot.

Applicants respectfully traverse this ground of rejection of claims 1, 4, 8-11, 17, 19-21, 24, 30, 78 and 446-447. It is believed that the subject matter of the instant claims, as amended herein, is not anticipated by Hess, as discussed below.

Independent claim 1, as amended, is directed to a “stent graft comprising an endoluminal stent and a graft, wherein the stent graft further comprises silk, wherein the silk induces a fibrotic response between the stent graft and animal tissue.” (emphasis added) Claims 4, 8-11, 17, 19-21, 24, 30, 78 and 446-447 depend either directly or indirectly from and include all the limitations of claim 1. Accordingly, claim 1, and all claims depending therefrom, are directed to a stent graft comprising a stent and a graft, and further comprising silk, wherein a

characteristic of the silk is that it induces a biological response, *i.e.*, a fibrotic response, within the tissue upon contact with the stent graft.

The Office Action asserts, with no further discussion, only that *Hess* “discloses a stent graft with the graft being made from a silk substantially as recited in the claims.” More particularly, *Hess* describes a “stent-graft composite intraluminal prosthesis” comprising a “tubular stent … and a polymeric stent sheath” wherein the “polymer is preferably selected from … spider silks ....” (*see, Abstract*) Further, *Hess* discloses and discusses use of such silk grafts to overcome lack of biocompatibility of conventional graft materials, such as polyester and nylon. Specifically, *Hess* discloses that “[r]eduction of implantation-related inflammation can be effected by selection of graft materials that are inherently more biocompatible than those heretofore employed in stent-graft devices.” (*see, paragraph [0015]*; emphasis added) In this regard, *Hess* further discloses that “[b]iological or bioengineered silk material … exhibits desirable characteristics which inhibit the inflammatory responses observed with other conventional polymeric materials used in stent-graft applications.” (*see, paragraph [0016]*; emphasis added) Thus, *Hess* teaches stent grafts having a stent and a graft, wherein the graft is made from silk and wherein a primary characteristic of the silk selected for use in the stent graft is its biocompatibility, that is, its inhibition of, or at least failure to induce, a biological response in the surrounding tissue.

Applicants thus submit that *Hess* fails to teach, or even suggest, the stent graft to which instant claim 1, as amended herein, and all claims depending therefrom, are directed. To summarize, *Hess* discloses a stent graft, having a stent and a graft, wherein the graft is made from a silk, and wherein the silk is such that the stent graft inhibits, or at least does not induce, a biological response between the stent graft and the surrounding tissue. In contrast, instant claim 1, as amended, is directed to a stent graft comprising a stent and a graft, and further comprising silk, wherein the silk is such that the stent graft induces a biological response between the stent graft and the surrounding tissue.

For at least the reasons discussed above, *Hess* does not disclose, or even suggest, the subject matter to which instant independent claim 1, as herein amended, is directed. Claim 1 is thus believed to be patentable over *Hess*. Further, dependent claims 2, 4, 8-11, 17, 19-21, 24,

30, 78, and 446-447 are also believed to be patentable over *Hess* because these claims depend either directly or indirectly from and include additional limitations to patentable independent claim 1.

Accordingly, Applicants submit that the rejection of claims 1-2, 4, 8-11, 17, 19-21, 24, 30, 78, and 446-447 under 35 U.S.C. § 102(e) has been overcome. Reconsideration and withdrawal of this rejection is respectfully requested.

***Rejection under 35 U.S.C. § 103***

Claims 3, 12, 14, 18-19, 22-23, 25-28, 70, 73-74, 76, 126-128, and 445 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Publication No. 2001/0053931 issued to *Hess et al.* (hereinafter “*Hess*”). In particular, the Office Action asserts only that *Hess* “discloses substantially the claimed invention, except for the limitations as recited in the [rejected] claims,” that the “limitations and their benefits to a patient are well known in the art,” and that it “would have been obvious ... to provide such limitations ... so that one can provide the benefits to a patient as one desires.”

Applicants respectfully traverse this ground of rejection. As discussed above, it is believed that *Hess* fails to teach, or even suggest, instant independent claim 1 and thus all claims depending therefrom. Further, it is believed that claim 1 itself, as amended herein, as well as claims 3, 12, 14, 18-19, 22-23, 25-28, 70, 73-74, 76, 126-128, and 445, which depend directly or indirectly from instant claim 1, would not have been obvious in view of *Hess* to one of skill in the relevant art at the time the invention was made.

As discussed above, instant claim 1, as amended, is directed to a “stent graft comprising an endoluminal stent and a graft, wherein the stent graft further comprises silk, wherein the silk induces a fibrotic response between the stent graft and animal tissue.” (emphasis added) That is, when implanted, the stent graft, comprising a stent and a graft, and further comprising a silk, induces a biological response between the stent graft and the tissue surrounding it.

Regarding *Hess*, as discussed above, this reference teaches a stent graft having a stent and a graft, wherein the graft portion is made from silk in order to overcome certain

problems associated with stent grafts having graft portions that are made from conventional polymeric materials. In particular, *Hess* describes such conventional stent grafts as “suffering from a lack of biocompatibility” and describes such “polymeric materials [as inducing] inflammatory responses in native vessels.” (*see, paragraph [0014] of Hess*) *Hess* further teaches that “[r]eduction of … inflammation can be effected by selection of graft materials that are inherently more biocompatible” and that “silk is a preferred covering because it is very biocompatible....” (*see, e.g., paragraphs [0015], [0016], [0040], and [0041] of Hess*) Further, as discussed above, *Hess* describes the stent graft, having a graft made from silk, as inhibiting, or at least not inducing, a biological reaction within the tissue surrounding the stent graft upon implantation.

Applicants submit that, not only does *Hess* fail to anticipate claim 1, and thus claims depending therefrom, but *Hess* also fails to provide the basis for an obviousness rejection of claim 1, or of the claims depending either directly or indirectly therefrom. Specifically, there is no sufficient reason provided in the Office Action for one of ordinary skill in the art to modify *Hess* to arrive at the stent graft claimed in the present application. In fact, as further discussed below, *Hess* teaches away from the use of silk in a stent graft as instantly claimed.

As discussed above, *Hess* teaches a stent graft, wherein the graft is made from silk, such that the stent graft inhibits, or at least does not induce, a biological reaction between the stent graft and the tissue surrounding it. Instant claim 1, as amended, and thus all claims depending therefrom, is directed to a stent graft having silk as an element to induce a biological reaction, *i.e.*, a fibrotic response, between the stent graft and the tissue surrounding it. Applicants respectfully submit that *Hess*’ teaching of a stent graft having a graft made from silk to improve biocompatibility would not lead a skilled individual to add silk to a stent graft to provide the stent graft with the ability to induce a biological response in tissue with which it is in contact. That is, a skilled individual seeking a material to incorporate into the graft portion of a stent graft in order to induce a fibrotic response in surrounding tissue would be discouraged by *Hess* from using silk as that material. *Hess* thus teaches away from the stent graft recited in instant claim 1 and the claims depending therefrom, in particular, claims 3, 12, 14, 18-19, 22-23, 25-28, 70, 73-74, 76, 126-128, and 445.

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Accordingly, for at least the reasons discussed above, Applicants submit that the rejection of claims 3, 12, 14, 18-19, 22-23, 25-28, 70, 73-74, 76, 126-128, and 445 under 35 U.S.C. § 103(a) has been overcome. Reconsideration and withdrawal of this rejection is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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